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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/890,801	10/30/2001	Stephen Edward Rees	0459-0683P	7859

2292 7590 10/06/2003

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EXAMINER

NASSER, ROBERT L

ART UNIT PAPER NUMBER

3736

DATE MAILED: 10/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/890,801

Applicant(s)

REES ET AL.

Examiner

Robert L. Nasser

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-50 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-50 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-50 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Applicant recites in the specification that the respiratory parameters are determined based on the measurement of blood oxygen and the measurement of oxygen in either inspiratory or expiratory air. However, applicant has not disclosed how this determination is made. In addition, with respect to claim 45, it is unclear why a healthy person would be suing the device, i.e. why would a healthy person need a ventilator. Clarification is required.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-50 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1, 15, and 30 are rejected in the word "means" is preceded by the word(s) "data storage" in an attempt to use a "means" clause to recite a claim element as a means for performing a specified function. However, since no function is specified by the word(s) preceding or following "means," it is impossible to determine the equivalents of the element, as required by 35 U.S.C. 112,

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sixth paragraph. See *Ex parte Klumb*, 159 USPQ 694 (Bd. App. 1967). Claim 1 is further rejected in that it is unclear what "respective oxygen levels" refer to. Claims 11-13, 26-28, and 41-43 are rejected in that the phrase "for example" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d). Claims 2-10, 14, 16-25, 29, 31-40, and 44-50 are rejected as being dependent on a rejected base claim.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 15, 18-20, 22, 24-26, 28-30, 33, 34, 37-39, 41, and 43, 44, 46-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shaffer et al. Shaffer et al shows a system that has a gas blender that mixes gas from two sources, an oxygen saturation measuring device (first detection means) that measures oxygen saturation and, if it deviates from a target level, adjust the fraction of inspired oxygen, which is measured with the processor (second detection means), to increase the oxygen saturation. In addition, the processor calculates several respiratory parameters (see column 5) and it includes a program to perform the process recited in claim 15. Claims 18-20 and 37-39 are rejected in that two respiratory parameters are determined based on two measurements (one each). With respect to claims 46-48, the device is useable on a person with COPD.

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Claims 1-14, 49, and 50 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, first and second paragraphs, set forth in this Office action. Claims 1-14 define over the art in that none of the art determines respiratory parameters, as defined in the specification, based on two concurrent measurements of inspiratory or expiratory oxygen levels and blood oxygen levels, as claimed.

Claims 16-21, 23, 24, 27, 31, 32, 35, 36, 40, and 42, would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, first and second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims. Claims 16, 17, 35, and 36 define over the art if record in that none of the art shows the recited third and fourth detection means. Claims 21 and 40 define over the art in that none of the art calculates the oxygen consumption, as claimed. Claims 23, 24, 31, and 32 define over the art in that none of the art shows the methods of assessing the change in oxygen levels. Claims 27 and 42 define over the art in that none of the art teaches using a gas with an oxygen level in the range claimed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Raemer, Mondry, Delpy, and Miles all show ventilator control systems that measure oxygen saturation and adjust the oxygen content of the inspired gas based thereon.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert L. Nasser whose telephone number is (703) 308-3251. The examiner can normally be reached on Mon-Fri, variable hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (703) 308-3130. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Robert L. Nasser  
Primary Examiner  
Art Unit 3736

RLN  
September 28, 2003



ROBERT L. NASSER  
PRIMARY EXAMINER